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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,427	12/12/2001	Harshal P. Bhagwatwar	U 013528-7	2278
140	7590	11/30/2004	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,427

Applicant(s)

BHAGWATWAR ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 3,9,18-51,53,56-62 and 64-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 10-17, 52, 54, 55, 63 and 69-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 06/04/04. Claims 1-71 are pending. Claims 3, 9, 18-51, 53, 56-62 and 64-68 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The rejection of claim 52 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method for suppressing serum testosterone, does not reasonably provide enablement for preventing or treating any health condition is withdrawn. However new claims 70 and 71 are rejected because of the preventing language. The discussion is as given in the previous office action.
2. Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites DNA fragments identified by applicants in the remarks to be genetic material. Applicants further acknowledge other materials such as RNA viruses as genetic materials. Applicants thus appear to claim materials that can be classified as genetic material and the meets and bounds of the genetic material cannot be ascertained.

Response to Arguments on restriction requirement

Applicants insist that the all claim 71 should be examined together because TWEENS are know and play no role in the formation of gelled dispersion and that all spans are water-insoluble and are incapable of gelling either the oil phase or the polymer solution phase. However, the requirement is proper and is maintained. Claim 3, for example, is directed to a non-biodegradable polymer while claim 2 is directed to biodegradable polymer. It is burdensome to

Art Unit: 1615

search for both biodegradable and non-biodegradable polymers. When allowable subject matter is identified and upon request by applicants, linking claims, if any, will be identified from the withdrawn claims, examined for patentability and rejoined with the allowable claims.

Claim Rejections - 35 USC § 103

3. Claims 1, 2, 5-8, 11-17, 52, 54, 55, 63 and 69-71 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,632,457).

Applicants argue that Sawhney discloses hydrogel matrix and differs from the instant claims thus:

- (a) Sawhney's continuous phase does not contain oil and is polymeric while the continuous phase of the instant claims contains oil and is formed by gelling the oil by sorbitan monostearate or sorbitan monopalmitate.
- (b) The instant claims comprise discontinuous phase that contains biodegradable or non-biodegradable polymer dissolved in a biocompatible water-soluble organic solvent and in Sawhney the discontinuous phase or hydrophobic domain is comprised of particles of waxes, fatty acid or fatty alcohols or oil and may also contain biologically active agent.
- (c) No preformed particles are used in the discontinuous phase of the instant claims while the discontinuous phase of Sawhney comprises preformed microparticles.
- (d) The discontinuous phase of the instant claims can release the active agent in a continuous controlled fashion over a prolonged period of time upon contact with aqueous fluid while the discontinuous phase of Sawhney rapidly release the drug/active agent upon contact with aqueous fluid.

Art Unit: 1615

(e) Composition of prior art swells upon contact with aqueous fluid while the instant composition does not swell upon contact with aqueous fluid.

(f) Microcarriers in the instant application is formed either in the body or in an external environment while in Sawhney the microcarriers are formed during the formation of the hydrogel.

(g) The instant composition falls apart into microcarriers upon contact with aqueous medium resulting in extremely significant specific surface area while the composition of Sawhney stays intact upon contact with aqueous medium with an insignificant change in specific surface area.

(h) The instant product is always available as a gelled dispersion that is ready for administration while the composition of Sawhney is a dry product that is implanted or dry microspheres where the viscosity of the product increases upon coming into contact with aqueous media.

Applicants admit that Sawhney discloses droplet-in-oil dispersion but that the droplet-in-oil dispersion of Sawhney differs from the claimed invention according the points described above.

4. Applicants' arguments filed 06/04/04 have been fully considered but they are not persuasive.

Regarding points (a), (b) and (c) it is noted that the instant claims that are examined are not drawn to continuous phase containing oil and/or discontinuous phase containing polymer. Regarding point (d) it is noted that the instant examined claims are not drawn to continuous phase containing oil and/or discontinuous phase containing polymer and the claims are not

Art Unit: 1615

directed to method of release of active agents or drugs. Regarding point (e), it is not immediately clear how the composition of the prior art would swell and the instant composition would not when the instant composition comprises a biocompatible, biodegradable or non-biodegradable polymer, pharmaceutically acceptable biocompatible emulsifier that is a sorbitan monostearate, sorbitan monopalmitate or a mixture thereof; which is the composition disclosed by Sawhney. Regarding point (f), how the microcarrier is made is not critical except the process by which the microcarrier is made produces a microcarrier that is structurally different. Regarding point (g), it is not immediately clear how the composition of the prior art would remain in tact in contact with aqueous medium and the instant composition would not when the instant composition comprises a biocompatible, biodegradable or non-biodegradable polymer, pharmaceutically acceptable biocompatible emulsifier that is a sorbitan monostearate, sorbitan monopalmitate or a mixture thereof; which is the composition disclosed by Sawhney. Regarding point (h), it is noted that both compositions are droplet-in-oil dispersion and applicants on page 18 of the remarks admit that.

5. Claims 4 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,632,457) and further in view of Borisy et al. (US 6,569,853).

Applicants state that Sawhney differs from the instant claims as per points (a) through (h) and that release pattern and the mechanism of delivery are different.

6. Applicants' arguments filed 06/04/04 have been fully considered but they are not persuasive.

As explained above, Sawhney discloses the composition of generic claim 1 and mechanism or delivery and release pattern would be inherent properties of the composition.

Art Unit: 1615

In general, the features upon which applicants center the argument on are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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